REMARKS

Claims 19and 41 to 44 have been amended and new Claims 74 to 85 have been added above, to more particularly point out and distinctly claim Applicants' invention.

Claim 19 has been rejected under 35 U.S.C. §112, second paragraph. The Examiner's attention is directed to the amendments to the claims above, which are believed to overcome this rejection.

Claims 41-45 have been rejected under 35 U.S.C. §102(b) as being anticipated by Pless et al., U.S. Patent No. 5,456,706 ("Pless"). The Examiner maintains that Pless is capable of meeting the functional use recitations presented in the claims.

Claims 41-45 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hoffmann et al., U.S. Patent No. 5,534,022 ("Hoffman"). The Examiner maintains that Hoffmann is capable of meeting the functional use recitations presented in the claims.

Claims 41-45 have been rejected under 35 U.S.C. §102(b) as being clearly anticipated by Kieval, U.S. Patent No. 5,814,079 ("Kieval"), and Claims 41-45 have been rejected under 35 U.S.C. §102(b) as being anticipated by Noren et al., U.S. Patent No. 5,649,966 ("Noren"). Claims 41-45 have also been rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under U.S.C. §103(a) as obvious over, Scherlag, U.S. Patent No. 5,083,564 ("Scherlag").

Applicants respectfully traverse the above rejections

The Examiner's attention is directed to the argumentation set forth on pages 18 to 27 of the previously filed Amendment Under 37 C.F.R. §1.116, which argumentation is incorporated herein by reference in its entirety and not further repeated herein.

The invention herein is not suggested or disclosed by the prior art cited by the Examiner. All of the cited prior art devices comprise electrodes for either pacing or defibrillation/cardioversion. It is only reasonable to assume that all of the inventors of the prior devices would design the electrodes on their leads to deliver the pacing or defibrillation signals in the most efficient way possible.

Also, it is well known in the art that the pacing threshold, i.e. the minimal voltage/current needed to excite the tissue, is highly dependent on the current density, and therefore it is important to keep the total geometrical surface area of a pacing electrode small. To achieve higher effective surface area (higher capacity) without increasing the geometrical dimensions of the electrode (thus keeping same current density) the electrodes are coated to create sub-structures in the surface area. However, given the electrode dimensions used for implantatable chronic pacing, even with the best coating materials (e.g., iridium-oxide, titanium-nitride, which almost reach the theoretical limit on how much the capacitance can be increased) the capacitance is still relatively small, i.e., considerably under 300μF. For example, the St. Jude Medical 1388T lead, which is considered to be one of the highest capacitance chronic pacing leads available, has a capacitance of less than 150 μF.

A defibrillation electrode must have a very high initial (geometrical) surface area to deliver defibrillation shock to a large volume (so that the tissue will not be damaged). However, to enable the electrodes to withstand chronic delivery of signals such as those used for contractility modulation without deteriorating, defibrillation electrodes must be coated. One of the results of these two limitations is that the capacitance of a coated defibrillation electrode is significantly higher than 3000μF.

The delivery electrodes of the present invention have capacitance of 300 - 3000 microfarads (see, page 20, Claim 41, and Claim 43) and impedance in the range of 50-500 ohms (page 22, Claim 83, and Claim 84). These values are clearly outside of the ranges of those known in the art to be beneficial for producing either pacing or defibrillation signals.

Since it would not have occurred to any skilled person trying to develop a lead capable of delivering either pacing or defibrillation signals (as was the case with the inventors of the cited prior art publications) to compromise the efficiency of his or her device by using electrodes having parameters similar to those of the lead of the invention, it must be concluded that the lead of the invention is both novel and inventive over the cited prior art.

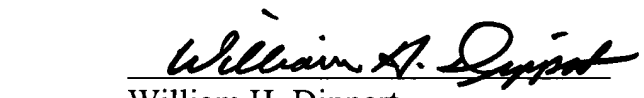
In view of all of the above, and especially taking into account the fact that the present invention is directed to providing for the first time an apparatus that is uniquely able to provide a new type of therapeutic signal for modifying the activity of a tissue, Applicants respectfully request that the Examiner review the amendments above and the comments above and then reconsider the bases of the rejections under §§ 102(b) and 103(a). It is earnestly believed that these rejections have been overcome and should be withdrawn.

Should the claims herein be allowable but for minor matters that could be the subject of either a supplemental submission by Applicants or an Examiner's Amendment, Applicants would appreciate the Examiner's contacting Applicants' undersigned attorney. In the alternative, Applicants would appreciate the opportunity to conduct an interview with the Examiner prior to issuance of another Office Action and respectfully request that the Examiner contact Applicants' undersigned attorney to discuss a mutually convenient time for doing so.

Reconsideration and allowance of all the claims herein are respectfully requested.

Respectfully submitted,

June 10, 2005



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